2401 W. Hassell Road
Suite 1535
Hoffman Estates, IL 60169
p 847.884.6117
f 847.884.6118
www.lifespine.com

510(k) Summary
LIFE SPINE® Stand-Alone Spacer System

Submitted By:

Life Spine, Inc.
2401 W. Hassell Road, Suite 1535
Hoffman Estates, IL 60169
Telephone: 847-884-6117
Fax: 847-884-6118

510(k) Contact:

Michael S. Butler
Life Spine, Inc.
2401 W. Hassell Road, Suite 1535
Hoffman Estates, IL 60169
Telephone: 847-884-6117
Fax: 847-884-6118

DEC 15 2009

Date Prepared: May 1, 2009

Trade Name: LIFE SPINE® Stand-Alone Spacer System

Common Name: Intervertebral Body Fusion Device

Classification: Class II

Product Code: MAX – Intervertebral Fusion Device with Bone Graft, Lumbar
21 CFR 888.3080 – Intervertebral Body Fusion Device

Predicate Devices:
Life Spine Plateau® Spacer System (K080411)
Blackstone PILLAR™ SA PEEK Spacer System (K081849)
Synthes SynFix™-LR (K072253)
Biomet Solitaire™ PEEK-Optima® (K081395)
Surgicraft STALIF™ TT (K073109)

Device Description:

The Life Spine Stand-Alone Spacer System implants are intervertebral body fusion devices comprised of a variety of spacer implants manufactured from Polyetheretherketone (PEEK-OPTIMA LT1) with tantalum markers. The spacers are hollow to permit packing with bone graft to help promote intervertebral body fusion. The superior and inferior surfaces have teeth to assist in the interface with the vertebral endplates to help prevent rotation and/or migration. Additionally, the implants incorporate a titanium alloy (6AL-4V-ELI per ASTM F-136) anterior fixation plate which has integrated screw holes to allow for placement of four titanium alloy screws that anchor the implant to the adjacent vertebrae. The implants are available in a range of sizes and footprints to suit the individual pathology and anatomicial conditions of the patient.

Life Spine®
2401 W. Hassell Road
Suite 1535
Hoffman Estates, IL 60169
p 847.884.6117
f 847.884.6118
www.lifespine.com

Intended Use of the Device:

The Life Spine Stand-Alone Spacer System System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). It is to be used in patients who have had at least six months of non-operative treatment. This device is intended to be used with autogenous bone graft.

The Life Spine Stand-Alone Spacer System System is intended for use with four titanium alloy screws which are provided with the system. If the physician chooses to use fewer than four of the provided screws, then a supplemental internal spinal fixation system that is cleared for use in the lumbosacral spine must be used.

Substantial Equivalence:

The Life Spine Stand-Alone Spacer System was shown to be substantially equivalent to previously cleared devices in indications for use, design, function, and materials used.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 12 2011

Life Spine, Inc.
% Mr. Michael S. Butler
President & CEO
2401 West Hassell Road, Suite 1535
Hoffman Estates, Illinois 60169

Re: K091301
Trade/Device Name: Life Spine Stand-Alone Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: November 24, 2009
Received: November 25, 2009

Dear Mr. Butler:

This letter corrects our substantially equivalent letter of December 15, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Life Spine®

2401 W. Hassell Road
Suite 1535
Hoffman Estates, IL 60169
p 847.884.6117
f 847.884.6118
www.lifespine.com

Indications for Use

510(k) number (if known): K091301

Device Name: LIFE SPINE® Stand-Alone Spacer System

The Life Spine Stand-Alone Spacer System System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). It is to be used in patients who have had at least six months of non-operative treatment. This device is intended to be used with autogenous bone graft.

The Life Spine Stand-Alone Spacer System System is intended for use with four titanium alloy screws which are provided with the system. If the physician chooses to use fewer than four of the provided screws, then a supplemental internal spinal fixation system that is cleared for use in the lumbosacral spine must be used.

Prescription Use x (Part 21 CFR 801 Subpart D)	And/Or	Over-the-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091301